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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/397,110	09/16/1999	NORMAN JAMES MOORE		8332

7590 04/15/2003

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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	**PAPER NUMBER**
1645	15

DATE MAILED: 04/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/397,110	Moore et al
Examiner	**Art Unit**
Portner	1645

-- The MAILING DATE of this communication appears on th cover sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 6, 2003* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-9, 33-40, and 42-51* is/are pending in the application.

4a) Of the above, claim(s) *1-9* is/are withdrawn from consideration.

5) ☒ Claim(s) *33-40 and 42-49* is/are allowed.

6) ☒ Claim(s) *50 and 51* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 10-32, 41 and 52-54 have been canceled.

Claims 1-9 and 33-51 are pending; Claims 1-9 are non-elected, withdrawn claims.

Claims 33-40, 42-51 are under consideration; 43, 45 and 50 are amended claims.

CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER FINAL REJECTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 6, 2003 has been entered.

Allowable Subject Matter

2. Claims 33-40, 42, claims 43-49 define allowable subject matter, as the prior art of record does not teach nor reasonably suggest the claimed combination of methods steps for detecting Streptococcus pneumoniae in a liquid sample.

Claim Objections/Rejections Withdrawn

3. Claims 43-49 objected to under 37 CFR 1.75© as being in improper form because a multiple dependent claim must depend from a previous claim in the alternative; claim 43 depends

from claims 42 and 33 simultaneously which is improper, in light of the amendment of claim 43 into independent form and no longer depends from claim 33.

4. Claim 43, step (e), rejected under 35 U.S.C. 112, second paragraph for reciting non-corresponding methods steps and not further limiting claim 33 from which it depends, because claim 43 further comprises additional methods steps or changes the methods steps all together, in light of the amendment of claim 43 to be an independent claim that sets forth a series of methods steps to detect Streptococcus pneumoniae C-polysaccharide.

5. Claim 52, section b) rejected under 35 U.S.C. 112, paragraph for reciting the phrase "said test strip", in light of the claim having been canceled.

6. Claims 52-54(C-polysaccharide antigen species)rejected under 35 U.S.C. 103(a), as previously applied to claims 50-51, as being unpatentable over Imrich (US Pat. 5,415,994) in light of Gribnau et al (US Pat. 4,373,932, incorporated by reference in Imrich, col. 5, line 37) in view of Krook et al (1987), in light of the claims having been canceled.

7. Claims 52-54(C-polysaccharide antigen species) rejected under 35 U.S.C. 103(a), as previously applied to claims 50-51, as being unpatentable over May et al (WO88/08534) in view of Krook et al (1987), in light of the claims having been canceled.

8. Claims 50-51 are rejected under 35 U.S.C. 103(a), as being unpatentable over Imrich (US Pat. 5,415,994) in light of Gribnau et al (US Pat. 4,373,932, incorporated by reference in Imrich, col. 5, line 37) in view of Krook et al (1987), in light of the amendment of claim 50 to utilize polyvalent antibodies.

9. Claims 50-51 rejected under 35 U.S.C. 103(a), as previously applied to claims 50-51, as being unpatentable over May et al (WO88/08534) in view of Krook et al (1987), in light of the amendment of claim 50 to utilize polyvalent antibodies.

New Claims Limitations/New Grounds of Rejection

Claim Rejections - 35 U.S.C. § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 50-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over May (WO88/08534) in view of Sundberg-Kovamees et al (1996) in light of Friesen et al (evidence provided to show state of the art as of 1989)

May et al teach and show an immunochromatographic device (see figures, and title) for the detection of clinically significant (see page 17, line 17-18) Streptococcus antigen (see page 17, line 10) is a sample, wherein the device comprises a housing with a window (see page 24, line 6 "aperture"), the housing containing a bibulous (porous, see page 23, lines 12) material having first and second zone that comprise polyvalent antibodies (a cocktail of monoclonal antibodies or a polyclonal antisera raised against a particular streptococcal antigen, see page 19, lines 9-11). The window in the housing is over the second zone (see page 24, lines 2-3). The first zone comprises a movably embedded conjugate of a labeling agent (see page 23, lines 35-36), the agent being gold sol (see page 31, paragraphs 1-3; page 36, lines 5-22, especially lines 21-22) attached to a Streptococcus specific antibody (see page 17, line 10) and the second zone

comprising a immovably bound stripe (see page 19, lines 13-14) of antibodies specific for Streptococcus (see May et al, all figures; page 16, lines 1-8).

May et al teach the utilization of polyvalent (cocktail of antibodies, see page 19, line 9) or polyclonal antibodies (see page 19, line 11) specific to Streptococcus antigens for the detection of pathogenic streptococci, but differs from the instantly claimed invention by failing to show the polyclonal streptococcal antibodies to be affinity purified streptococcal antibodies directed against streptococcal C-polysaccharide antigen.

Sundberg-Kovamees et al (1996) teach affinity purified polyclonal antibodies, directed against streptococcus C-polysaccharide antigen(see page 224, paragraph 2, bottom of paragraph) in an analogous art for the purpose of showing an immunoassay format to detect whole pneumococci expressing C-polysaccharide, extracts containing C-polysaccharide antigen and purified C-polysaccharide epitopes in a sample (see page 231, paragraph 3).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the device of May et al with the polyclonal affinity purified anti-C-polysaccharide antibodies of Sundberg-Kovamees et al because Sundberg-Kovamees et al teach, show and provide guidance for the utilization of affinity purified polyvalent antibodies directed against C-polysaccharide antigen, wherein the antibodies were able to detect whole pneumococci expressing C-polysaccharide, extracts containing C-polysaccharide antigen and purified C-polysaccharide epitopes in a sample (see page 231, paragraph 3) and May et al teaches that

polyclonal antibodies directed against Streptococcus are readily incorporated into an immunochromatographic device.

The person of ordinary skill in the art would have been motivated by the reasonable expectation of success, in light of the state of the art being one that readily adapts heterologous immunoassay formats as taught by Sundberg-Kovamees et al, into an immunochromatographic device immunoassay (see Friesen et al, state of the art as of 1989, col. 6, lines 49-55), for the attainment of a device that can conduct an assay in 10 minutes or less (see May et al,page 2, lines 6-7).

In the absence of a showing of unexpected results, May et al in view of Sundberg-Kovamess et al obviates the instantly claimed invention directed to an immunochromatographic device that comprises polyclonal (polyvalent) antibodies for the detection of Streptococcus, specifically Streptococcus pneumoniae through the detection of C-polysaccharide antigen, a major surface component of pneumococci associated with colonization and spread of respiratory infection caused by Streptococcal pathogens (see Sundberg-Kovamees et al, abstract, and introduction section page 223) because Sundberg-Kovamees et al showed that the polyclonal affinity purified antibodies were highly specific for C-polysaccharide antigen and correlates with S.pneumoniae infection and May et al teaches the utilization of anti-streptococcal polyclonal antibodies that can be formulated into first and second zones, the first zone comprising a movably labeled polyclonal and the second zone comprising an immobilized polyclonal.

Claim Rejections - 35 U.S.C. § 112

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 50 has been amended to define the bibulous material strip to be "equipped with a window in the housing". As subsections a) and b) of claim 50 are set forth the define the bibulous material and what it has (see amended claim 50, line 4), the recitation that the second zone being "equipped with a window in the housing" is unclear as the bibulous material has not been set forth to comprise a housing nor a window.

Conclusion

14. This is a non-final action.

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

16. EP 0497524 A2 is cited to show C-polysaccharide of S.pneumoniae.

17. Rehg et al (US Pat. 6,194,221) is cited to show an immunochromatographic device that comprises first and second zones which comprise first and second polyclonal antibodies directed against group A streptococcus (see claims 14 and 15).

18. Sjorgren et al (1987) is cited to show alpha hemolytic strains of Streptococcus, Streptococcus pneumoniae and Streptococcus mitis express C-polysaccharide antigen.
19. Sjorgern et al (1987, J. Immunol. Methods) is cited to show that alpha streptococci and pneumococcal C-polysaccharide strains cross react when the polyclonal antibodies are not affinity purified against the phosphorylcholine determinant in C-polysaccharide.
20. Stuertz et al (1998) is cited to show an immunoassay directed against streptococcus polysaccharide C epitope utilizing polyclonal antibodies (EIA, page 2346, col. 2).
21. Tuomanen et al(US Pat. 6,495,139) is cited to show a pneumococcal choline binding protein.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242. The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp
April 9, 2003

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